



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug Stores
For
U.S. House of Representatives
Subcommittee on Health
Hearing on:
“Examining Drug Compounding”
May 23, 2013
10:00 a.m.
2322 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee on Health for consideration of our statement for the hearing “Examining Drug Compounding.” We look forward to our continued work with you on ensuring that Americans receive safe and effective compounded prescription drugs.

NACDS commends the Committee for your efforts to better understand issues related to the compounding of prescription drugs. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their over \$1 trillion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

Introduction

NACDS supports the mission and work of FDA in ensuring that Americans receive only safe and effective prescription drugs. Safeguarding the health and welfare of our patients remains our highest priority. Pharmacist compounding services are the only source of critical medications for millions of patients who each have their own unique health care needs. For these patients, there are no commercially-manufactured preparations available. Accordingly, we agree with FDA that prescription drug compounding services are a valuable and important part of our nation’s healthcare system.

Background on Compounding

Prescription drug compounding has been a traditional function of the practice of pharmacy ever since the beginning of the profession. Compounding is an important component of patient care because many patients need prescription products that are not made commercially by drug manufacturers. Compounding by pharmacists is the only way to meet these patients' needs. Traditional prescription drug compounding is based on individual prescription orders for individual patients for products that are not commercially available. Because of these patient needs compounding continues to be an integral function of pharmacy practice.

Pharmacists are trained to prepare compounded medications and are tested on this competency. State boards of pharmacy license pharmacies after ensuring, among other things, that they have the proper tools and equipment to compound prescription drug medications.

The definition of what constitutes "compounding" is consistent from state to state. Generally, it involves the mixing of two or more drug substances together to deliver to the patient a product that is not commercially available. Most retail pharmacies engage in the compounding of skin creams, lotions, ointments, liquids, or suppositories. For example, chain pharmacists helped to meet the need for liquid Tamiflu during the 2009 H1N1 flu outbreak through their ability to compound the liquid product from Tamiflu capsules – and at the request of FDA. In other cases, a pharmacist may be called on to compound a liquid form of a medication for a patient battling cancer, when that patient is not able to swallow the pill form of the medication.

Some chain pharmacies may have a local or regional central compounding facility that they use to compound frequently-ordered products that are not commercially available, which are then distributed to individual retail stores in the chain. These compounded products are made in anticipation of prescriptions for these products based on the prescribing patterns of physicians.

Preserving State Board Authority

NACDS believes that state boards of pharmacy should retain sole jurisdiction over traditional prescription drug compounding. This is a proper role for state pharmacy boards. Prescription drug compounding has been an integral function of the practice of pharmacy since the early days of the profession. State boards of pharmacy have the experience and expertise to continue to regulate this integral function. We urge the Committee to continue to maintain this policy. We believe that state boards of pharmacy should continue to regulate functions that are the practice of pharmacy, while FDA should regulate the manufacturing of prescription drugs. FDA should not be granted authority over traditional pharmacy functions. FDA would not have the resources, ability or expertise to regulate pharmacies and the practice of pharmacy. Moreover, concurrent state and federal jurisdiction over pharmacies would cause unnecessary confusion for FDA, state boards of pharmacy, and pharmacies. All would be unsure as to where federal authority ends and state authority begins.

State and Federal Collaboration

We support efforts among FDA and the state boards of pharmacy to work together to investigate any questionable practices so that prescription drug compounding is regulated in the best interests of patients. To prevent future tragedies, there must be a close collaboration among FDA and the boards of pharmacy. Despite best efforts, there still may be entities that seek to circumvent patient safety measures as well as federal and state regulation. We support state and federal joint efforts to root out rogue entities that seek to use a state pharmacy license as a shield from federal oversight.

Conclusion

NACDS thanks the Committee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.